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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,551	08/01/2001	Renu B. Lal	14114.0346U2	4683

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,551

Applicant(s)

LAL ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet.*

Continuation of Attachment(s) 6). Other: Notice to Comply with Requirements for Patent Applications containing Nucleotide Sequence Disclosure and/or Amino acid Sequence Disclosure.

DETAILED ACTION

Claims 1-19 are pending in this application. An IDS filed 12/10/01, Paper No. 3 has been received and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

Priority

The instant application is a 371 of PCT/US00/02498 filed 2/1/2000 which claims benefit of US Provisional 60/118,357, filed 2/3/1999. Support for SEQ ID NO: 6-9 and for the citation of specific nucleotide positions of 4550, 4596, 4625, 4626, 4724, 4753, 4754, 4956, 4984, 4985, 5051, 5080, 5126 of HIV-1 of the HXB2 strain is not found in the priority document 60/118,357. Therefore, a priority date of 2/1/2000 will be attributed to these limitations.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 10, line 19. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Sequence Compliance

The application contains sequence disclosures that are encompassed by the definition for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, the application fails to comply with the requirements of 37 C.F.R. 1.821(a)(1) and (a)(2) for the reasons set forth in the attached Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequence Disclosures And/Or Amino Acid Sequence Disclosures. Specifically, a statement that the CRF and the paper copy of the Sequence Listing are the same is missing.

Drawings

The drawings are objected to because Figure 2 is described in the Brief Description of Drawings as Figure 2A and 2B. However, Figure 2 does not contain an A and B portion. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 6, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonough et al. EP 0617132 A2, publication date 12/30/1998 (applicant cited), see entire document.

McDonough et al teach oligonucleotides primers chosen from regions corresponding to the following nucleotides from HXB2, 4756-4778, 4835-4857 and 4952-4969 (page 4, line 1-5). The primers were used to detect HIV-1 by amplification of a conserved region of pol (see e.g. page 7, line 55 and page 9, line 50).

Claims 1, 6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Respass, US 5,599,662 (February 4, 1997).

Respass teaches the use of primers for amplification of a nucleic acid sequence from the pol gene of HIV-1 (see e.g. abstract). A primer pair was designed that amplifies sequences from 4750 to 4990 of HXB2 HIV-1 (see e.g. column 5, line 59-67 and table 1). Respass teaches use of the primer pairs to detect HIV-1 by PCR amplification (see e.g. column 15, line 1-36).

Claims 1-2, 4-7, 9, 10-11 and 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Pieniazek et al HIV Sequence Database (1998) p 1-6, applicant cited, see entire document.

Pieniazek et al teach use of nested primers pairs GP40F1 and GP41R1 and GP46F2 and GP47R2 that correspond to SEQ ID NO: 1-4 (see e.g. page 2582, column 1, paragraph 5). These primers are used to detect HIV-1 subgroups by PCR amplification (see e.g. Figure 1).

Claims 1, 3-6, 8-10 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Backus et al. EP 0 887 427 A2 (applicant cited), see entire document.

Backus et al. teach methods and test kits for the detection of all known HIV-1 subtypes and/or HIV-2 subtypes (page 2, line 33-35). Backus et al teach that "Primers were designed to conserved regions" of HIV-1 (see e.g. page 9, line 54-58). Primers were ultimately designed to hybridize to conserved regions of pol and env. SEQ ID NO: 9 of the instant invention shares 100% homology with base pairs 3 to 31 of the primer on page 9, line 25 (SEQ ID NO 8) and therefore hybridizes to a region between 4550 and 5126 of the HXB2 strain and can be expected to selectively hybridize to HIV-1. SEQ ID NO: 8 form a primer pair with SEQ ID NO 27 or 7 (which binds between 4897 to 4924 of HXB2) to amplify HIV-1 nucleic acids in the sample, both of which were selected from highly conserved region of HIV-1 and HIV-2. Several probes between 18-40 nucleotides were designed to detect the regions amplified by the PCR primers (see e.g. page 5, line 6-41 and page 11, line 51-54).

Claims 1, 3-6, 8-10 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Backus et al. US 6,001,558, see entire document.

Backus et al. teach methods and test kits for the detection of all known HIV-1 subtypes and/or HIV-2 subtypes (abstract). Backus et al teach that "Primers were designed to highly

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conserved regions" of HIV-1 (see e.g. column 10, line 50-65) that include pol and env (see e.g. column 3-5). SEQ ID NO: 9 of the instant invention shares 100% homology with base pairs 3 to 31 of the primer on page 9, line 25 (SEQ ID NO 8) and therefore hybridizes to a region between 4550 and 5126 of the HXB2 strain and can be expected to selectively hybridize to HIV-1. SEQ ID NO: 8 form a primer pair with SEQ ID NO 27 or 7 (which binds between 4897 to 4924 of HXB2) to amplify HIV-1 nucleic acids in the sample, both of which were selected from highly conserved region of HIV-1 and HIV-2 (see e.g. column 10, line 50-65). Several probes between 18-40 nucleotides were also designed to detect the regions amplified by the PCR primers (see e.g. column 15).

Claims 1, 2, 4, 6, 10 and 15 rejected under 35 U.S.C. 102(e) as being anticipated by Delaporte et al. US 2003/0180759, see entire document.

Delaporte et al teach methods of detecting HIV-1 and HIV-2 with the use of nested PCR primers (see e.g. page 25, paragraph 0447). Outer primers sense 41-1 and antisense 41-4 bind at 7785-7818 and 8347-8379 respectively. Exact binding sites of the inner pair could not be determined as they were designated according to HIV-1 Ant70 sequence and not HXB2 but as it is an inner primer set, it will bind in the region between 7746 and 8459.

Claims 1-2, 4-7, 9, 10-11 and 13-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Yang et al. J of Clinical Microbiology (Aug 1999) p 2581-2586, applicant cited, see entire document.

Yang et al teach use of nested primers pairs GP40F1 and GP41R1 and GP46F2 and GP47R2 that correspond to SEQ ID NO: 1-4 (see e.g. page 2582, column 1, paragraph 5). These primers are used to detect HIV-1 subgroups by PCR amplification (see e.g. Figure 1).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1-19 are vague for reciting that the oligonucleotides primer “selectively hybridizes”. The term “selectively” is a relative one not defined by the claim, no single set of conditions is recognized by the art as being “selective” and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established.

Claims 5, 9, 13, 15 and 19 are unclear for reciting primers with nucleic acids with conservative substitutions thereof. As conservative substitutions typically describe alterations in amino acid sequences, it is unclear how the Nucleic acid primers can have conservative substitutions.

Claim 17 is unclear for reciting that the first primer comprises the nucleotide sequences of SEQ ID 5-9. It is unclear how a single primer can be comprised of 5 divergent nucleic acid sequences.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 7-8, 10, and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants claim a genus of nucleic acid primers that selectively hybridize to a highly conserved region of a **nucleic acid** molecule of HIV-1 between nucleotide positions 4550-5126 or 7746 to 8459.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. In the instant case, applicants do not disclose any primers that will bind to a highly conserved region of a **nucleic acid** sequence between nucleotides 4550-5126 or 7746-8459. The sequence is to be designed to detect HIV-1 from a sample. By claiming a primer hybridizable to a **nucleic acid**, the relationship between the structure of the sequence and its function becomes unclear. Given the diversity of nucleic acid sequences that should be detected by a primer that corresponds to a nucleic acid from HIV region 4550-5126 or 7746-8459 and the uncertainty that this sequence

will be HIV-1, it must be considered that any primer that binds to HIV-1 must be empirically determined. In an unpredictable art, the disclosure of no examples in a genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.


Conclusion

Claims 1-19 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


GERRY LEFFERS
PRIMARY EXAMINER

Maria B Marvich, PhD
Examiner
Art Unit 1636

September 30, 2003